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10/578,135	05/02/2006	Peter Osypka	SMB-PT172(PC 05 079 M US)	5225

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,135	OSYPKA, PETER	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/2/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/2/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the power supply, as claimed in claim 12; the evaluation unit for additional processing of the detected data, as claimed in claim 14; the measurement device having a plurality of sensors, as claimed in claims 15 and 25; a dosing element for controlled release of the material, as claimed in claim 17; and the transmitter, receiver, and evaluation unit being coupled to the measurement device via the optical fiber cable, as claimed in claim 21 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 5, 8, and 15 are objected to because of the following informalities:

On line 2 of claim 5, "the magnet" should be replaced with "a magnet".

On line 1 of claim 8, "the measurement device" should be replaced with "the at least one sensor and at least magnetic element of the holder". It is noted that claim 1, upon which claim 8 depends recites that a portion of the measurement device is not inserted in the body cavity.

On line 2 of claim 15, "comprising" should be replaced with "comprises".

On line 2 of claim 15, "the sensors" should be replaced with "and the sensors". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites, "one of the magnetic elements is arranged inside of the body cavity and the other of the magnetic elements is arranged

outside of the body cavity". Claim 4 recites, "the magnetic element (5) arranged inside of the body cavity". Each of claims 5 and 9 recites, "magnetic element (5) arranged outside of the body cavity". The human body is non-statutory subject matter and cannot positively be claimed. This rejection may be overcome by replacing "arranged" with "adapted to be arranged" in all instances.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 8, 9, 12, and 19 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US Patent Application Publication No. 2003/0014742 to Lewkowicz et al. Lewkowicz discloses a measurement device comprising at least one sensor (see entire document, especially paragraphs 11, 25 of Lewkowicz) and a holder having at least one first and one second magnetic element, of which at least one is a magnet (see entire document, especially paragraphs 22, 23, claim 3 of Lewkowicz). One element is arranged inside the body cavity and the other is arranged outside the

cavity. The measurement device is adapted to be fixed by the holder in the cavity (see entire document, especially figs. 1A, 4A; paragraphs 12, 23 of Lewkowicz).

Regarding claim 4 the at least one sensor is connected rigidly to the magnetic element 27 inside the body cavity (see entire document, especially fig. 2; paragraphs 10, 28, 29 of Lewkowicz).

Regarding claim 6, the measurement device is adapted to be moved within the body cavity by rearranging or shifting the magnet, wherein the magnet shifts in response to the signal, thereby moving the sensor with it (see entire document, especially paragraphs 7, 10, 22, 23 of Lewkowicz).

Regarding claim 8, the measurement device is capable of being inserted in the body cavity via an implantation instrument, catheter, or the like (see entire document, especially fig. 4A; paragraph 29 of Lewkowicz).

Regarding claim 9, the magnetic element outside of the body is capable of being applied to a surface of the body (see entire document, especially figs. 1, 4A of Lewkowicz).

Regarding claim 12, the measurement device is provided with a power supply 25 (see entire document, especially figs. 2; paragraphs 28 of Lewkowicz).

Regarding, claim 19, on the measurement device, there is a transmission device through which the measurement device is capable of being connected to a transmitter, receiver, and evaluation unit arranged outside the body using wireless connection (see entire document, especially paragraph 28 of Lewkowicz).

Claims 1-6, 8-10, 12, 16, 17, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2004/0050394 to Jin. Jin discloses a measurement device comprising at least one sensor (see entire document, especially paragraph 16 of Jin) and a holder. The holder has at least one first magnetic element arranged inside of the body cavity and a second magnetic element arranged outside of the body cavity, wherein the measurement device is adapted to be fixed by the holder in the cavity (see entire document, especially fig. 3; paragraphs 14, 15 of Jin).

Regarding claims 2 and 3, one magnetic element is a magnet and the other is a part made from ferromagnetic material, wherein both elements are magnets (see entire document, especially paragraphs 14, 15 of Jin).

Regarding claim 4, the at least one sensor is connected rigidly to the magnetic element arranged in the body cavity (see entire document, especially figs. 3, 4a & b of Jin).

Regarding claim 5, the magnetic element arranged outside of the cavity is a magnet (see entire document, especially fig. 3; paragraphs 14, 15 of Jin).

Regarding claim 6, the measurement device is adapted to be moved within the body cavity by rearranging or shifting the magnet, wherein the magnet shifts in response to the signal, thereby moving the sensor with it (see entire document, especially paragraphs 14, 15 of Jin).

Regarding claim 8, the device is capable of being inserted via implantation instrument (see entire document, especially figs. 3, 4a & b; paragraphs 14, 16 of Jin).

Regarding claim 9, the magnetic element arranged outside of the body cavity is capable of being applied to a surface of the body (see entire document, especially fig. 3; paragraphs 14, 15 of Jin).

Regarding claim 10, the measurement device is at least partially sheathed or encased in a flexible biocompatible material (see entire document, especially paragraph 14 of Jin).

Regarding claim 12, the measurement device is provided with a power supply (see entire document, especially paragraph 21 of Jin).

Regarding claim 16, at least one storage device is provided on the measurement device for housing a material to be introduced into the body cavity (see entire document, especially fig. 4b; paragraph 20 of Jin).

Regarding claim 17, a dosing element controls release of the material (see entire document, especially paragraph 20 of Jin).

Regarding claims 19 and 20, a transmission device is implied by the disclosure that the capsule can be controlled using magnetic or wireless RF signals. Through such a device, the measurement device is capable of being connected to any external device, including a transmitter, receiver, and/or evaluation unit (see entire document, especially paragraph 19 of Jin). With further regard to claim 20, the disclosure of communication with the capsule via magnetic or wireless RF signals also implies that transmission device has a radiation output for introducing electromagnetic radiation (magnetic or wireless RF signals) into an interior of the body cavity, wherein the capsule resides in the cavity (See entire document, especially paragraph 19 of Jin).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10, 11, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,442,413 to Silver in view of US Patent Application Publication No. 2003/0014742 to Lewkowicz et al. Regarding claims 1, 10, 11, 23, and 24, Silver discloses a measurement device comprising stent cage 14 having a sensor 20. The stent 14 is positionable within a body cavity via a catheter (see entire document, especially figs. 1A, 2, 7A-E; col. 9, lines 39-65; col. 10, lines 20-44; col. 18, lines 14-67 of Silver). Silver lacks a holder comprising a first magnetic element to be arranged within the body cavity and a second magnetic element to be arranged outside of the cavity.

However, Lewkowicz teaches a means for positioning an implantable sensor within a body cavity, wherein the means for positioning comprises a holder including at least one first magnetic element positioned within the cavity and a second magnetic element positioned outside of the cavity (see entire document, especially figs. 1A, 2, 4A, 4B; paragraphs 7, 23, 29 of Lewkowicz). Therefore, it would have been obvious to one of ordinary skill in the art to use the means for positioning of Lewkowicz in place of the

catheter of Silver, as it would merely be the substitution of one known means for positioning for another.

Regarding claim 10, the measurement device is at least partially sheathed or encased in a flexible, biocompatible material (see entire document, especially col. 11, lines9-col. 11, lines 33-58 of Silver).

With further regard to claim 11, he measurement device and an electronic component arranged on the device are provided with an additional coating(see entire document, especially fig. 1A; col. 11, lines 3-32; col. 20, lines 19-26 of Silver)

Regarding claim 24, the measurement device is integrated at least partially into a lattice structure of the stent cage (see entire document, especially figs. 1A, 2; col. 10, lines 20-44 of Silver).

Claims 7, 13, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jin, as applied to claims 1-6, 8-10, 12, 16, 17, 19, and 20 above, and further in view of US Patent No. 6,477,406 to Turcott. Jin lacks a plurality of sensors, but states that the capsule may comprise a diagnostic device. However Turcott discloses a diagnostic device comprising a plurality of sensors (see entire document, especially fig. 1; col. 9, lines 43-55 of Turcott). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the device of Turcott as the diagnostic device of Jin, since Jin discloses using a diagnostic device, and Turcott discloses an appropriate such device.

Regarding claim 13, an electronic memory unit is included capable temporary storage of data (see entire document, especially col. 9, lines 43-65 of Turcott).

With further regard to claim 14, an evaluation unit 102 processes detected data and is provided in a region of the sensor (see entire document, especially co. 9, lines 43-61 of Turcott).

Regarding claim 15, the sensors are provided for detecting values of the body cavity and/or a medium located therein (see entire document, especially col. 9, lines 43-55 of Turcott).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewkowicz, as applied to Claims 1, 4, 6, 8, 9, 12, and 19 above, and further in view of US Patent No. 6,689,056 to Kilcoyne et al. Lewkowicz lacks a thread holder. However, Kilcoyne discloses an implantable, positionable measurement device, wherein the device has a thread holder 122 (see entire document, especially fig. 4; col. 9, lines 42-54 of Kilcoyne). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the thread holder of Kilcoyne with the device of Lewkowicz in order to provide a means for long term positioning or attachment.

Allowable Subject Matter

Claims 18 and 25 are rejected under 35 U.S.C. 101, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and to overcome the 101 rejection

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 18, the primary reason for allowance is the inclusion of the measurement device being part of a control loop and the dosing element releasing the material as a reaction to a measurement value detected by the sensor, in combination with all of the other limitations of the claims, which is not found in the prior art.

Regarding claim 25, the primary reason for allowance is the inclusion of the plurality of sensors being connected to the magnetic elements and arranged in a plane of the stent cage in a uniformly distributed arrangement, in combination with all of the other limitations of the claims, which is not found in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Examiner, Art Unit 3735